REMARKS

Claims 2-19 are pending.

In the Office Action mailed January 5, 2010, the Examiner rejected Claim 17 under 35 U.S.C. 102(b) as being anticipated by Epshtein RU Patent No. 2104006 (RU '006). Claims 14-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over RU '006, as applied to claim 17, and further in view of Epshtein et. al., RU Patent No. 2099052 (RU '052). Claims 2-13 are rejected under 35 U.S.C. 103(a) as being unpatentable RU '006, in view of RU '052, as applied to claims 14-16, 18, and 19, and further in view of Epshtein et. al., PCT/RU01/00239 (PCT '239), and Epshtein et. al., PCT/RUO2/00369.

Applicant respectfully requests consideration and allowance of all pending claims in view of the remarks set forth below.

I. Rejection of claim 17 under 35 USC § 102(b)

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Epshtein RU '006. The Examiner states that RU '006 discloses a method of combining potentiated morphine with the habitual morphine dose to enhance effectiveness of treating withdrawal symptoms and thus RU '006 anticipates claim 17.

Applicant disagrees.

Claim 17 recites as follows:

> 17. A method of enhancing the activity of an active pharmaceutical substance, wherein said active pharmaceutical substance is morphine, upon administration to a subject suffering from a condition or disorder treatable by said active pharmaceutical substance, said method comprising combining a therapeutic dose of said active pharmaceutical substance with a homeopathically activated form of said active pharmaceutical substance.

To anticipate a claim, a reference must disclose either explicitly or inherently, each

element of the claim "as set forth in the claim." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131.

Contrary to the Examiner's assertion, Epshtein RU '006 does not disclose combining a potentiated morphine with a therapeutic dose to enhance the effectiveness of morphine. RU '006 simply discloses that homeopathic dilutions of morphine may be administered with the narcotic (which may also be morphine) obtained by homeopathic procedures. Thus, RU '006 actually discloses administration of potentiated morphine in combination with the potentiated habitual narcotic again obtained by homeopathic procedures (See Ex. 12). The cited art of record does not disclose a method of enhancing the activity of morphine by combining a therapeutic dose with a homeopathically activated form of morphine.

Thus, Epshtein RU '006 does not disclose each element as set forth in claim 17, either explicitly or inherently. Accordingly, withdrawal of the anticipation rejection of claim 17 is respectfully requested.

II. Rejection of claims 14-16, 18 and 19 under 35 USC § 103(a)

Claims 14-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Epshtein RU Patent No. 2104006 (RU '006), as applied to claim 17 above, and further in view of Epshtein et. al., RU Patent No. 2099052 (RU '052). The Examiner states that it would have been *prima facie* obvious, at the time of the invention, to one of ordinary skill in the art, to enhance the activity of ethanol by administering a combination of ethanol which has been prepared by homeopathic dilutions (as per RU '052) along a therapeutic dose of ethanol, because the RU '006 patent teaches that this method is effective for enhancing the activity of morphine.

Applicant disagrees.

To establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP 2143.02; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). First, there must be some teaching, suggestion or motivation, either in the references themselves or in the knowledge generally

available to one of ordinary skill in the art, to modify the reference or to combine teachings of the prior art to achieve the claimed invention. Second, there must be a reasonable expectation of success. Finally, while the prior art reference (or references when combined) need not explicitly teach or suggest all the claim limitations, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Thus, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Unless all of the three criteria are met, a conclusion of obviousness cannot be reached. MPEP §2141.02.

The teaching, suggestion or motivation test has been modified by *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007). To support obviousness, *KSR* still requires a showing that "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007).

Claims 14 reads as follows:

> 14. A method of enhancing the activity of an active pharmaceutical substance, wherein said active pharmaceutical substance is ethanol, upon administration to a subject suffering from a condition or disorder treatable by said active pharmaceutical substance, said method comprising combining a therapeutic dose of said active pharmaceutical substance with a homeopathically activated form of said active pharmaceutical substance.

Claims 15-16 depend from claim 14 and claims 18-19 depend from 17. The claims are directed to methods of enhancing the activity of ethanol by treating ethanol with a homeopathically activated from of ethanol. Applicant has discovered that when a therapeutic dose of an active compound is combined with a homeopathic dose, the combination results in a potentiation of the pharmacological activity of the compound and/or reduction in the undesired side effects.

First, RU '006 does not teach combining a therapeutic dose of morphine with a homeopathically activated form of morphine in order to enhance the activity of morphine. Instead, RU '006 discloses administration of homeopathic dilutions of morphine and the habitual

narcotic also obtained by homeopathic procedures. RU '052 discloses homeopathic dilutions of ethanol. Neither of the cited references suggests or provides any reason to modify a therapeutic dose of ethanol in the manner of the claimed invention. Thus, the cited references alone or in combination, simply do not teach, suggest or provide any reason to enhance the activity of ethanol in the manner of the claimed invention. As set forth above, *KSR* continues to require that the prior art provide a reason for the modification in the direction of the invention. The prior art could not have provided the requisite reason because the very reason for the modification is the essence of the present discovery. Thus, one skilled in the art would not have any reason, in view of the cited art, to modify a therapeutic dose of ethanol in the direction of the claimed combination or to modify a homeopathic dilution of ethanol to include a therapeutic dose.

Second, The Examiner did not set forth art that provides the requisite "reasonable expectation of success." Neither the cited references, nor the art at the time the present application was filed, provide one skilled in the art with any expectation of obtaining the results provided in the claimed invention; namely, that the homeopathically activated form will modify the properties of the therapeutic dose of ethanol. The specification shows that administration of the combination of claim 14 is more potent than therapeutic dose of ethanol alone or homeopathically activated dilutions of ethanol alone, (see Example 6, page 6 of the specification), establishing that the treatment with homeopathic dilution significantly modifies the properties of a therapeutic dose of ethanol. None of the cited art suggests the surprising result that the administration of a therapeutic dose of an active pharmaceutical substance in combination with a homeopathically activated form of the active pharmaceutical substance would enhance the activity of the active pharmaceutical substance. Thus, one skilled in the art would not have had a reasonable expectation of success.

Third, the Examiner has not set forth prior art that teaches or suggest all limitations of the claim. The cited art alone or in combination doe not teach or suggest the combination of claim As stated above, the '006 reference does not disclose combining a therapeutic dose of morphine with a homeopathically activated form of morphine in order to enhance the activity of morphine. RU '052 fails to overcome the deficiency of RU '006. The cited art alone or in combination simply do not teach or suggest combining a therapeutic dose of ethanol with a homeopathically

activated form of ethanol to enhance the activity of ethanol. Thus, the art cited by the Examiner does not teach or suggest all limitations of the claim 14.

In conclusion, Applicant asserts that the Examiner has failed to meet the criteria required to support a *prima facie* case of unpatentability. Accordingly, withdrawal of the obviousness rejection of claim 14 and dependent claims 15-16 is respectfully requested. Claims 18 and 19 depend from claim 17 and withdrawal of the obviousness rejection for claims 18 and 19 is also respectfully requested.

III. Rejections of claims 2-13 under 35 USC § 103

Claims 2-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over RU '006, in view of RU '052, as applied to claims 14-16, 18, and 19 above, and further in view of Epshtein et. al., PCT/RU01/00239 (PCT '239), and Epshtein et. al., PCT/RUO2/00369 (PCT '369). The Examiner states that PCT '239 discloses that compound such as phenazepam, diazepam and hydrocortisone are used for the treatment of various medical conditions and PCT '369 teaches that cyclophosphamide is useful for medicinal purposes. Thus, he concludes that it would have been obvious to enhance the activity of such compounds by the same methodology as disclosed in the combined teachings of the '006 and '052 patents.

Applicant disagrees. As stated above, to establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP 2143.02; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006).

Independent claim 2 recites a method of enhancing the activity of phenazepam Independent claim 5 recites a method of enhancing the activity of diazepam. Independent claim 8 recites a method of enhancing the activity of hydrocortisone. Independent claim 11 recites a method of enhancing the activity of cyclophosphamide.

First, as stated above, RU '006 does not teach combining a therapeutic dose of morphine with a homeopathically activated form of morphine in order to enhance the activity of morphine.

Instead, RU '006 discloses homeopathic dilutions of morphine and the habitual narcotic also obtained by homeopathic procedures. RU '052 discloses homeopathic dilutions of ethanol. None of the cited references suggests or provides any reason to modify a therapeutic dose of an active pharmaceutical substance in the manner of the claimed invention. Thus, the cited references alone or in combination, simply do not teach, suggest or provide any reason to enhance the activity of phenazepam, diazepam, hydrocortisone or cyclophosphamide in the manner of the claimed invention. As set forth above, *KSR* continues to require that the prior art provide a reason for the modification in the direction of the invention. The prior art could not have provided the requisite reason because the very reason for the modification is the essence of the present discovery. Thus, one skilled in the art would not have any reason, in view of the cited art, to modify a therapeutic dose of an active pharmaceutical agent in the direction of the claimed combination or to modify a homeopathic dilution of an active pharmaceutical agent to include a therapeutic dose.

Second, The Examiner did not set forth art that provides the requisite "reasonable expectation of success." None the cited references, nor the art at the time the present application was filed, provide one skilled in the art with any expectation of obtaining the results provided in the claimed invention; namely, that the homeopathically activated form will modify the properties of the therapeutic dose of an active pharmaceutical agent. The specification shows that administration of the combination as claimed in claims 2, 5, 8 and 11 is more potent than pharmaceutical substance alone or homeopathically activated dilutions of alone, (see Example 1-2 and 4-5, pages 2-3 and 5-6 of the specification), establishing that the treatment with homeopathic dilution significantly modifies the properties of a therapeutic dose of phenazepam, diazepam, hydrocortisone and cyclophosphamide. None of the cited art suggests the surprising result that the administration of a therapeutic dose of an active pharmaceutical substance in combination with a homeopathically activated form of the active pharmaceutical substance would enhance the activity of the active pharmaceutical substance. Thus, one skilled in the art would not have had a reasonable expectation of success.

Third, the Examiner has not set forth prior art that teaches or suggest all limitations of the claim. The cited art alone or in combination doe not teach or suggest the combination of claim

As stated above, the '006 reference does not disclose combining a therapeutic dose of morphine with a homeopathically activated form of morphine in order to enhance the activity of morphine. RU '052, PCT '239 and PCT '639 all fail to overcome the deficiency of RU '006. The cited art alone or in combination simply do not teach or suggest combining a therapeutic dose of an active pharmaceutical substance with a homeopathically activated form of the active pharmaceutical substance to enhance the activity of the active pharmaceutical substance. Thus, the art cited by the Examiner does not teach or suggest all limitations of the claims 2-13.

In conclusion, Applicant asserts that the Examiner has failed to meet the criteria required to support a *prima facie* case of unpatentability. Accordingly, withdrawal of the obviousness rejection of claims 2-13 is respectfully requested.

IV. Provisional Rejections of claims 2-19

The Examiner rejected the claim 2-19 of the present application over co-pending and co-assigned application No. 09/117838. Applicant will provide an appropriate Terminal Disclaimer in the present or the cited co-assigned applications at the point in prosecution when no other rejection shall remain.

The Applicant therefore respectfully request reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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